

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VIIV HEALTHCARE UK LTD. and VIIV
HEALTHCARE CO.,

Plaintiffs,

v.

LUPIN LTD., LUPIN
PHARMACEUTICALS, INC., and
TEVA PHARMACEUTICALS, INC.,

Defendants.

REDACTED -- PUBLIC VERSION

C. A. No. 11-cv-00576-RGA
(CONSOLIDATED)

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO SANCTION
DEFENDANTS FOR EXCEEDING SCOPE OF EXPERT REPORTS**

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Defendants Lupin Ltd., Lupin Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. (collectively, “Defendants”) jointly submit this Opposition to Plaintiffs’ Motion to Sanction Defendants for Exceeding Scope of Expert Reports (“ViiV’s motion”). For the reasons set forth below, ViiV’s motion should be denied in its entirety.

I. ViiV’s Motion to Strike Is Without Merit.

ViiV incorrectly asserts that Drs. Parniak, Arnold and Laurence testified beyond the scope of their expert reports. ViiV’s motion to strike such testimony therefore should be denied.

a. Dr. Parniak Did Not Testify Beyond the Scope of His Expert Reports.

ViiV’s allegations regarding the scope of Dr. Parniak’s trial testimony and expert reports are incorrect. Dr. Parniak testified that the subject matter of independent claim 20 (on which asserted claims 26, 27, 29 and 30 depend) is obvious in view of the following combinations:

- (1) New AIDS Therapies 1994 (TTX 196) / Daluge 1994 (TTX 265, Ab. I6) / Tisdale 1994 (TTX 265, Ab. I82) and Hart 1992 (TTX 124) / Coates 1992 (TTX 56) / Schinazi 1995 (TTX 224) (*see* T579:19-584:20; Ex. A, TDX 6, at 2); or
- (2) AIDS Alert 1995 (TTX 17) / Schinazi 1995 (TTX 224) / DeNoon 1995 (TTX 71), Du 1992 (TTX 78), and Daluge 1994 (TTX 265, Ab. I6) (*see* T584:21-587:14, 590:23-591:15; TDX 6, at 3-4¹).

Dr. Parniak fully disclosed combination (1) in his expert reports. Under the heading “New AIDS Therapies 1994 and Hart 1992,” Dr. Parniak opined that Hart 1992, as well as Coates 1992 and Schinazi 1995, taught that ddC had toxicity problems, whereas ddC’s close analog, 3TC, was far less toxic. Ex. B, Opening Report ¶¶ 383, 385; *see also id.* ¶¶ 165-172, 191, 356-358. This background knowledge provided a motivation to replace ddC with 3TC in the ABC+ddC combination that was disclosed in New AIDS Therapies 1994, as well as in Daluge 1994 and Tisdale 1994. *Id.* ¶¶ 381, 382, 384-387; *see also id.* ¶¶ 201-208, 214, 363.

ViiV’s assertion that Dr. Parniak “added and relied on Schinazi 1993 (TTX 225) and

¹ Slide 3 of TDX 6 also identifies Katlama 1995 and Staszewski 1995 (TTX 91, in evidence as TTX 28), studies which are reported on in AIDS Alert 1995 (TTX 17). T594:2-595:4.

DeNoon 1995 (TTX 71)” for combination (1) is wrong. ViiV Motion at 4 (citing T590:23-591:15). Dr. Parniak’s testimony at 590:23-591:15 does not relate to combination (1) and actually described “slide three” of TDX 6 – *i.e.*, combination (2), which properly included both Schinazi 1995 and DeNoon 1995. His reference to “TTX 225” was a mistake due to an obvious typographical error on slide 3, which led him to refer to Schinazi 1995 (TTX 224) incorrectly as TTX 225. *Compare* TDX 6 at 3, *with id.* at 2. He discussed Schinazi 1995 (TTX 224) during his direct examination (*see, e.g.*, T562:10-T564:11) but did not discuss Schinazi 1993 (TTX 225) until cross examination, when ViiV first offered TTX 225 into evidence (T627:2-13, 630:9-13).

Dr. Parniak also disclosed combination (2) in his expert reports. Under the heading “AIDS Alert 1995 (Reporting on Katlama 1995 and Staszewski 1995), Du 1992, and Daluge 1994,” Dr. Parniak opined that AIDS Alert 1995 taught the clinical success of the AZT+3TC combination, and that Schinazi 1995 and DeNoon 1995 taught the same thing. *Id.* ¶¶ 369-370; *see also id.* ¶¶ 185-193. Dr. Parniak also opined that Du 1992 taught a motivation to modify AZT+3TC by replacing AZT with a comparably potent but less toxic alternative, like carbovir. *Id.* ¶¶ 370-371. Dr. Parniak further opined that Daluge 1994 taught that ABC was an even better AZT-alternative than carbovir. *Id.* ¶¶ 372-374; Ex. C, Reply Report ¶¶ 525-527.

ViiV incorrectly asserts Dr. Parniak added Tisdale 1994 (TTX 265), WO ‘159 (TTX 201), and Schinazi 1995 (TTX 224) to combination (2). D.I. 211 at 4. Dr. Parniak’s testimony about Tisdale 1994 at 584:9-20 referred to “the second slide of TDX 6”—combination (1)—which included Tisdale 1994. His testimony at 583:20-584:4 was in the context of “the first slide” of TDX 6 (T583:10-11) and appropriately described POSAs’ background knowledge²

² A court may “look to ... background knowledge possessed by a person having ordinary skill ... to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

about HIV therapy from WO '159 and Schinazi 1995 that provided a motivation to combine NRTIs. *See, e.g.*, Ex. B ¶¶ 354-366.

ViiV's argument incorrectly implies that Dr. Parniak's 130-page Opening Report consisted only of Paragraph 353, a cursory introductory paragraph that on its face and in the context of the Report is not exhaustive or claim-specific. D.I. 211 at 3; T572:15-18. ViiV's focus on that one paragraph, to the exclusion of Dr. Parniak's full discussion of the art that he relied upon for his opinions (Ex. B ¶¶ 366-374, 381-387) and his full explication of the knowledge in the field at the time, is a distortion of the record, as Teva's counsel explained at trial. T573:8-574:13. The record shows that ViiV had full notice of Dr. Parniak's opinions and the bases therefor, and his trial testimony was fully consistent with the opinions disclosed in his reports. *Tracinda Corp. v. DaimlerChrysler AG*, 362 F. Supp. 2d 487, 506-07 (D. Del. 2005) (Farnan, J.) (finding "no justification for excluding [expert] testimony" that "was consistent with and not materially different from the opinions contained in his expert report").

b. Dr. Laurence Did Not Testify Beyond the Scope of His Expert Reports.

ViiV complains that Dr. Laurence provided testimony on two new references, AIDS Alert 1995 (TTX 17), and DeNoon 1995 (TTX 71). ViiV Motion at 4-5. As it did at trial, ViiV only cites Dr. Laurence's opening report and refuses to acknowledge both references were discussed in his reply report—a fact not lost on this Court. T697:20-22 ("...I gather that what Mr. Molino is saying is [that the references are] in the reply expert report."). Paragraphs 16 and 61 of Dr. Laurence's Reply Report disclose that both references, among others, demonstrated that the combination of AZT and 3TC were consistently shown to be effective in clinical trials. *See* Ex. D, Reply Report ¶¶ 16 and 61. Lupin uses both references in its Opening Post-Trial Brief on Invalidity consistent with Dr. Laurence's description from his Reply Report. *See e.g.*,

D.I. 202, at 5-6 (“The AZT/3TC prospective human trials established proof of this principle in humans, producing a sustained, tenfold viral load reduction for a period of over a year.”) (citing Dr. Laurence’s direct testimony at trial). Further, ViiV’s own expert, Dr. Ho, testified about these same references; Lupin also cites to Dr. Ho’s testimony. *See e.g., id.* at 3-6. Thus, ViiV has no basis to complain about Dr. Laurence’s testimony.

c. Dr. Arnold Did Not Testify Beyond the Scope of His Expert Reports.

ViiV, not Lupin, was the party that: (1) asked Dr. Arnold to opine on “any suggestion ... when looking at the universe of drugs one could combine for anti-HIV therapy;” T822:13-23; (2) asked whether a preferred combination would include NNRTI’s; *id.*; and (3) implied combining drugs “with overlapping resistance profiles” would not “provide a resensitization benefit” to any “good researcher”. T828:4-830:11. ViiV cannot complain about Dr. Arnold’s redirect testimony prompted by ViiV’s cross examination questions and a portion of an exhibit ViiV discussed on cross. T830:14-16. His testimony was “based on this” reference. T831:18-19. Dr. Arnold was not asked about this portion of the reference during his direct examination. Lupin’s Opening Post-Trial Brief on Invalidity also does not rely solely on this testimony, but uses it in conjunction with other trial testimony. D.I. 202, at 14 and 16. ViiV also has no basis to complain when the testimony is supported by that given by others at trial.³

II. ViiV’s Motion for a New Trial Is Improper.

The Court allocated the parties five pages “*to move to strike*” offending testimony. T1482:9-24. ViiV’s motion for a new trial is improperly beyond the scope of the Court’s order and should be denied on that basis. ViiV fails to identify a legal basis to seek a new trial. ViiV

³ It is unclear what ViiV’s real complaint is. ViiV states that Dr. Arnold testified about the St. Clair Abstract (D.I. 211 at 5). But Dr. Arnold does not identify this reference; nor can ViiV complain that Dr. Arnold relied on this reference since his reports discuss this abstract in detail.

only cites to Fed. R. Civ. P. 26(a) and 37(c)(1) – neither of which provides for a new trial. In any event, ViiV’s motion for a new trial should be denied because, even if Drs. Parniak, Arnold and Laurence testified beyond the scope of their reports (which ViiV cannot show), ViiV has not even alleged that it has suffered any undue prejudice.⁴ *McMillan v. Weeks Marine Inc.*, 478 F. Supp. 2d 651, 659 (D. Del. 2007) (“For a party to prevail on this argument, it *must demonstrate* that the expert’s testimony exceeded the scope of the Rule 26 report, and *that the objecting party suffered undue prejudice because of the violation.*”) (emphasis added).

The cases cited by ViiV involve motions for new trials under Rule 59(a) (a rule that ViiV never mentions in its motion) that were submitted after jury verdicts.⁵ Neither case supports ViiV’s request for a new trial. *Belden* is inapposite because the Court there granted a new trial only because the defendants had “assured the court that they did not intend to argue” obviousness, yet their expert repeatedly did so at trial in front of the jury. *Belden Techs. Inc., v. Superior Essex Commc’n LP*, 802 F. Supp. 2d 555, 566 n.6 (D. Del. 2011). In *McMillan*, a personal injury case, the Court determined that the plaintiff’s expert testified beyond the scope of his expert reports and his expertise, and found *undue prejudice* because that testimony was “integral to the jury’s verdict on lost wages.” *McMillan*, 478 F. Supp. 2d at 659.

III. Conclusion

For the reasons set forth above, Defendants respectfully submit that ViiV’s motion be denied in its entirety. Defendants also request that ViiV be precluded from seeking a new trial after the Court issues its invalidity opinion because it would unfairly prejudice Defendants.

⁴ ViiV has not raised any objections to the scope of Dr. Zingman’s trial testimony, which on its own is sufficient to support a finding of invalidity for claims 26, 27, 29 and 30. For that reason alone, the Court should deny ViiV’s motion for a new trial with respect to those claims.

⁵ “[A] trial judge sitting without a jury is entitled to even greater latitude concerning the admission or exclusion of evidence.” *In re Unisys Savings Plan Litig.*, 173 F.3d 145, 156 (3rd Cir. 1999) (internal citation omitted).

Dated: July 17, 2013

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